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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,412	08/28/2003	Nicholas Thomas	HO-P02190US1	6563
26271	7590	03/21/2005		
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			EXAMINER BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,412

Applicant(s)

THOMAS ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003 and 01 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-52 is/are pending in the application.
- 4a) Of the above claim(s) 41-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/673,169.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/28/03 & 1/21/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 20-40, drawn to a microfabricated cell assay device, classified in class 435, subclass 288.5.
 - II. Claims 41-52, drawn to cellular assays, classified in class 435, subclass 29.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group II and Group I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as an assay that does not require cells. The device can be used to assay proteins and/or other analytes that are capable of being filter and/or specifically bound within a test region in which the analytes can be optically analyzed.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. During a telephone conversation with Melissa W. Acosta on 3/10/2005 a provisional election was made with the preservation of the right to traverse to prosecute the invention of Group I, claims 20-40. Affirmation of this election must be made by applicant in replying to this Office action. Claims 41-52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statements filed 8/23/03 and 1/21/04 have been considered and made of record.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 19, 22-25 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,319,469) and Zuk et al.(WO 97/07993).

The reference of Sheppard, Jr. et al. discloses an assay device and method of use which includes a disk device that includes a plurality of micro-channel elements (shown in Figure 2). Each element includes a cell growth chamber (24) which allows cells to be introduced and cultured for attachment (See column 4, lines 14-17). The reference discloses detection of test compounds on the cultured cells (See column 7, lines 13-32 and Example 3).

Claim 20 first differs by reciting specific construction limitations such as the use of multiple micro-channel elements and cover limitations.

The reference of Sheppard, Jr. et al. discloses that the device as disclosed by Mian et al. can be used to construct the system of Sheppard, Jr. et al. (See column 3, lines 28-38 which makes reference to Application 08/768,990 in the specification of Sheppard, Jr. et al.).

The reference of Mian et al. discloses a base and cover construction for forming a plurality of micro-channel elements (See Figure 1B).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the construction techniques of Mian et al. to construct the device of Sheppard, Jr. et al. for the known and expected result of providing a device as is required of the Sheppard, Jr. et al. reference.

Claim 20 further differs by reciting that the device includes “a hydrophobic barrier or valve in at least one of said chambers or said channels”.

The references of Sheppard, Jr. et al. and Mian et al. disclose that the use of valves to control the flow of liquid between the chambers of the device is known (See column 13, lines 1-9; column 13, line 65, to column 14, line 30; and column 20, lines 12-67, of the reference of Sheppard, Jr. et al.). The list of disclosed valves includes capillary microvalves wherein the fluid flow is stopped based on the geometry of the channel and surface properties of the substrate material and fluid.

The reference of Zuk et al. discloses that it is known in the art to control the flow of liquids within a rotary analytical device by modifying the surfaces of the inlet chambers and

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associated flow paths to be hydrophobic (See page 5, lines 1-25; page 9, lines 17-33; and page 10, lines 1-16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the hydrophobic treatment disclosed by the reference of Zuk et al. for controlling the flow of liquid within the device of the primary reference of Sheppard, Jr. et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result. The reference of Zuk et al. discloses that protein binding zones and fluid control zones can be formed with the same treatment process thus reducing manufacturing costs.

With respect to claim 22, the hydrophobic valve suggested by the reference of Zuk et al. would result in a localized region of hydrophobicity within a channel or chamber.

With respect to claims 23 and 24, the reference of Sheppard, Jr. et al. discloses that the device is intended to be used with a suspension of cells that are to be attached in the cell chambers (See column 4, lines 1-17).

With respect to claim 25, the device suggested by the combination of the references of Sheppard, Jr. et al. and Mian et al. would be a rotatable disc with a center inlet port and annular sample chamber.

With respect to claim 33, the reference of Sheppard, Jr. et al. discloses the use of three-dimensional surfaces for the cell accumulation chamber (See column 16, lines 38-42). With respect to the use of beads or pillars for cell attachment, the use of surface area extending surfaces in cell culture is well known in the art for the known and expected result of increasing

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the surface area of attachment for the cells to attach and thus increasing the number of cells which can be maintained within the cell culture chamber (24).

With respect to the use of inlet channels of one size verses an outlet of a smaller size of claims 34 and 35, the reference of Mian et al. discloses that it is known in the art to control the flow of liquid through a plurality of zones using changes in cross-sectional area between the zones (See column 19, lines 25-63).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide differences in cross-section between the inlet and outlet of the culture chamber and other chamber for the known and expected result of controlling the flow of liquid between the difference chambers.

With respect to claims 36-38, the claims differ by reciting the use of additional detection chambers for detecting metabolites released by the cell culture.

While the reference of Sheppard, Jr. et al. discusses the detection of cell metabolites, the reference does not detect them in a separate chamber. However, based on the plurality of different detection schemes disclosed by both the reference of Sheppard, Jr. et al. and the reference of Mian et al. (See the Examples of both references), it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide additional detection chamber separate from the culture chamber for the known and expected result of providing an alternative means recognized in the art to achieve the same result, detection of metabolites produced by the cultured cells in response to treatment agents exposed to the cells.

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11. Claims 21, 26 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,319,469) and Zuk et al.(WO 97/07993) taken further in view of Chen et al.(US 5,800,778).

The combination of the references of Sheppard, Jr. et al., Mian et al. and Zuk et al. has been discussed above.

Claims 21 and 26 further differ by reciting that one or more components (the cover) of the device are constructed of a gas permeable plastic material.

The reference of Chen et al. discloses that it is known in the art to employ a gas permeable cover in a test device which is constructed with a base including channels and chambers with the gas permeable cover. The reference discloses that the use of the cover provides increased growth rates from an enhanced oxygen environment (See column 3, lines 6-7).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the primary reference with a gas permeable cover member for the known and expected advantages disclosed by the reference of Chen et al.

With respect to the cell attachment means of claim 21, the reference of Sheppard, Jr. et al. discloses the use of non-specific cell adhesion coating (See column 4, lines 1-17).

With respect to the specifics of the cell attachment means of claims 29-31, the reference of Sheppard, Jr. et al. discloses the use of chemical surface treatments or the use of adhesion proteins (See column 16, lines 1-37). The specific adhesion protein employed would have been

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well within the purview of one having ordinary skill in the art using well known proteins such as collagen or fibronectin.

With respect to claim 32, the reference of Sheppard, Jr. et al. discloses the use of three-dimensional surfaces for the cell accumulation chamber (See column 16, lines 38-42). With respect to the use of beads or pillars for cell attachment, the use of surface area extending surfaces in cell culture is well known in the art for the known and expected result of increasing the surface area of attachment for the cells to attach and thus increasing the number of cells which can be maintained within the cell culture chamber (24).

12. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,19,469); Zuk et al.(WO 97/07993) and Chen et al.(US 5,800,778) taken further in view of Wolfe et al.(US 5,190,879).

The combination of the references of Sheppard, Jr. et al., Mian et al., Zuk et al. and Chen et al. has been discussed above.

While the reference suggest the use of a gas permeable cover, the above claims recite specific materials for the gas permeable material.

The reference of Wolfe et al. provide a list known materials which can be used as a gas permeable material in a culture device (See column 2, lines 39-68).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any of the known gas permeable materials as the cover member for the

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known and expected result of providing an alternative means recognized in the art to achieve the same result, provide gas exchange to a culture chamber.

13. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Mian et al.(US 6,319,469) and Zuk et al.(WO 97/07993) taken further in view of Cook (WO 94.26413).

The combination of the references of Sheppard, Jr. et al., Mian et al. and Zuk et al. has been discussed above.

While the reference of Sheppard, Jr. et al. discloses the use of optically detectable labels within the chambers (See column 3, lines 39-67), Claims 39 and 40 differ by reciting that the device includes a layer of a scintillant substance and includes a binding moiety.

The reference of Cook discloses that it is conventional in the art to study of the interaction of biological molecules with cultured cells using a layer of a scintillant substance and a binding moiety (See pages 9-17).

In view of this teaching, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ the scintillation assay technique disclosed by the reference of Cook in the system of the modified primary reference of Sheppard, Jr. et al. for the known and expected result of providing an art recognized means for observing cellular processes with respect to a reagent as is performed in the system of the modified primary reference.


Conclusion

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB